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Datasheet for the decision of 20 May 2015

Case Number: T 0859/11 - 3.2.02

Application Number: 01935533.8

Publication Number: 1284656

IPC: A61B17/00

Language of the proceedings: EN

Title of invention:
ALIGNMENT MEMBER FOR DELIVERING A NON-SYMMETRIC DEVICE WITH A PREDEFINED ORIENTATION

Patent Proprietor:
AGA Medical Corporation

Opponent:
Occlutech GmbH

Headword:

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

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It can be changed at any time and without notice.

Catchword:

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

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Case Number: T 0859/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 May 2015

Appellant: (Opponent)	Occlutech GmbH Wildenbruchstrasse 15 07745 Jena (DE)
Representative:	KIPA AB P O Box 1065 251 10 Helsingborg (SE)
Respondent: (Patent Proprietor)	AGA Medical Corporation 5050 Nathan Lane North Plymouth, MN 55442-2204 (US)
Representative:	Potter Clarkson LLP The Belgrave Centre Talbot Street Nottingham, NG1 5GG (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 February 2011 rejecting the opposition filed against European patent No. 1284656 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	C. Körber
	D. Ceccarelli

Summary of Facts and Submissions

I. On 18 February 2011 the Opposition Division posted its decision to reject the opposition against European patent 1 284 656.

II. An appeal was lodged against this decision by the opponent by notice received on 18 April 2011, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 28 June 2011.

III. By communication of 26 January 2015, the Board forwarded its provisional opinion to the parties and summoned them to oral proceedings.

IV. Oral proceedings were held on 20 May 2015.

The final requests of the parties were as follows:

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed, or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the auxiliary requests 1 to 3 filed with letter dated 17 December 2010.

V. The following documents are of importance for the present decision:

E1: EP-B1-0 891 757
E2: WO-A-00/12012.

VI. Claim 1 of the patent as granted reads (with the feature denotation proposed in the statement of grounds of appeal being indicated in the left margin):

"A delivery device suitable for delivering a collapsible device (14) to a pre-selected region within a patient, said delivery device comprising:
a) an elongated pusher catheter (10)
b) having a proximal end (28) and a distal end (30),
c) said distal end includes a distal tip having an alignment member (24) adapted for
d) mating with a connecting member (16) of the collapsible device, wherein
e) the orientation of the alignment member relative to a longitudinal axis of the elongated pusher catheter is predetermined to allow
f) only one orientation of the collapsible device relative to the longitudinal axis and
g) is further set relative to a bend fixed in the pusher catheter."

Claims 2 to 7 are dependent claims.

VII. The appellant's arguments are summarised as follows:

In addition to features a) to d), document E2 also disclosed features e) to g) of claim 1 of the main request. The mandrel (42) was tubular and suitable for pushing and could thus be equated to the elongated pusher catheter defined in feature a). The non-circular portion of the distal end (80) of the mandrel was oriented relative to its longitudinal axis, which was inherent to the construction of the guiding mandrel as seen in Figure 8A. The non-circular distal end (80) prevented movement of the collapsible device (page 15,

lines 3 to 32). Figures 5A and 5B showed the implant aligned relative to a bent shape of the delivery device. As the implant (68) was aligned by the distal end (80), i.e. the alignment member of the mandrel (Figure 11A), and the mandrel must be bent as the delivery device, the alignment member was set relative to the bent shape of the mandrel. Claim 1 therefore lacked novelty in view of E2.

If f) and g) were to be regarded as distinguishing features over E2, the underlying problems would be unrelated, without any synergistic effect. Feature f) served to prevent rotation and tilting of the collapsible device. As already suggested in E2 (page 15, lines 17 to 19), it was within the skilled person's general technical knowledge that a non-circular or asymmetric shape was suitable for this purpose. As became clear from the following lines 20 to 21, this shape did not only avoid coiling, but also served to achieve a specific deployment configuration of the collapsible device. Furthermore, E1 disclosed feature f) in form of the pusher button (120) which engaged the flange at the proximal end of the occlusive device, as described in paragraph [0042], thus holding it in place in only one orientation. The purpose of feature g), on the other hand, was to achieve alignment with the anatomy within the patient. It was also generally known that a bent structure was advantageous in this respect. Again, Figures 5A and 5B of E2 gave a clear hint in that direction. E1 also disclosed in paragraph [0040] that a curve aided in directing the distal end toward the specific delivery site of the occlusive device.

Claim 1 of the main request also lacked inventive step with E1 chosen as closest prior art in view of E2. The problem to be solved by feature g) was to ensure that

the collapsible device was delivered in a specific orientation. E1 already addressed the issue of aiding the directing of the device and taught that the catheter should be curved to allow this (paragraph [0040], lines 46 to 48). Although this paragraph mentioned the directing of the distal end, it was implicitly clear that any device attached to the distal end or delivered from the distal end would be aligned in the same direction, as seen in Figure 12, where the device to be delivered had the same orientation as the distal end of the bent catheter. In the wording of feature g), the term "fixed" was not limiting over the disclosure in E1. The guide wire in E1 had a fixed bend, as seen in Figure 12. In all cases, the bend in the catheter (100) was fixed, which forced the guide wire to assume the curvature of the catheter. The guide wire therefore also had a fixed bend in relation to the catheter. Further, it made no difference whether it was the catheter or the guide wire itself which was bent. The same effect was achieved, i.e. the device attached to the guidewire would be delivered in a specific orientation. The skilled person faced with the problem underlying feature g) would ensure that the guide wire in E1 was bent to ensure that the device was delivered in the desired orientation. Feature f) was disclosed in E1 in terms of the flange (70) of the device (50) having a threaded attachment for removably retaining the device as described in paragraph [0049]. Such threaded attachment secured the device relative to the bend in the pusher to make sure that it only had one orientation relative to the longitudinal axis and would be delivered in a specific orientation. This was also emphasised in paragraph [0048], line 53, stating that the "guide wire holds the occlusion device in place". Moreover, apart from having the bend of the pusher to ensure a specific orientation, the skilled person,

faced with the above problem, would recognize that rotation and tilting of the device had to be prevented as these were the possible directions of movement of an object in space. The threaded attachment would allow the skilled person to prevent tilting. Further, the threaded attachment would allow the skilled person to simply fixate the device (50) with sufficient force to prevent any rotational movement.

VIII. The respondent's arguments are essentially those on which the following reasons of this decision are based.

Reasons for the Decision

1. The appeal is admissible.

2. Novelty – main request

Document E2 discloses, in the wording of claim 1, a delivery device (62) suitable for delivering a collapsible device (68) to a preselected region within a patient (Figures 5A to 5E), said delivery device comprising:
a) an elongated pusher catheter (the guiding mandrel 42, which is tubular as mentioned in line 32 of page 12, is considered to be suitable for the purpose of pushing)
b) having a proximal end and a distal end (Figure 5D),
c) said distal end includes a distal tip having an alignment member (80 in Figure 8B) adapted for
d) mating with a connecting member (44) of the collapsible device (page 15, lines 6 to 10), wherein
e) the orientation of the alignment member (80) relative to a longitudinal axis of the elongated pusher catheter (42) is predetermined (Figure 8B).

E2 fails to disclose, however, that the orientation of the alignment member relative to a longitudinal axis of the elongated pusher catheter is predetermined to allow
f) **only one** orientation of the collapsible device relative to the longitudinal axis and
g) is further **set** relative to a bend **fixed** in the pusher catheter.

As clearly shown in Figure 8B of E2, the oblate shape of the distal tip (80) of the mandrel, corresponding to the alignment member in claim 1, allows not only one orientation, but two orientations of the collapsible device (68) which can sit on the mandrel with its eyelet (44) positioned as depicted in Figure 8A, or in a position turned by 180°. As stated in lines 9 to 12 of page 15, the mandrel is designed to be in any non-circular shape that prevents rotation or twisting of the mandrel relative to the eyelet. The other shapes mentioned in the following lines 13 to 16 also serve this purpose. None of them allows **only one orientation** of the collapsible device relative to the longitudinal axis.

Moreover, the mandrel (42), corresponding to the pusher catheter in claim 1 as mentioned above, does not comprise a bend fixed therein. There is no explicit disclosure of this feature in E2. It is true that the delivery catheter (62) may comprise a bend as shown in Figures 5A to 5C and Figures 14A and 14B (which may be regarded as "fixed" in view of the relevant part of the description at page 18, line 28 to page 19, line 3). This implies that the mandrel (42), with the attached closure device (68), when located within the delivery catheter (62) as for instance shown in Figure 14A, must also be bent in that position. But it cannot be derived therefrom that it comprises a **fixed** bend.

Since E2 thus fails to disclose a fixed bend, it can also not be said that the orientation of the alignment member relative to the longitudinal axis of the pusher catheter is **set** relative to a **bend fixed** in the pusher catheter, as required by claim 1.

It follows that the subject-matter of claim 1 of the main request is novel vis-à-vis E2 within the meaning of Article 54 EPC.

3. Inventive step – main request

Document E2 is the closest prior art since it also deals with a device for delivering a collapsible device to a preselected region within a patient by means of a pusher catheter.

By virtue of the distinguishing features f) and g) it is possible to achieve the technical effect of delivering the collapsible device to the delivery site in a pre-determined rotational orientation relative to the longitudinal axis of the pusher catheter, as explained in paragraphs [0006] and [0016] of the patent in suit. This is particularly advantageous if the collapsible device is non-symmetric as mentioned in paragraph [0001] and shown in Figures 3 and 4. Both features f) and g) in combination contribute to achieving this technical effect: the bend may be designed to match the shape of a blood vessel adjacent the delivery site, with the single possible orientation of the collapsible device being set (and thus fixed and known) relative to this bend located adjacent to the delivery site.

The objective technical problem solved by the claimed invention is to provide a device which allows a more

precise and better controlled delivery of the collapsible device to a specific site in a patient.

In document E2, the rotational orientation of the collapsible device (68) about the longitudinal axis of the guiding mandrel (42) is of no importance and not addressed anywhere. As explained in the last paragraph of page 15, the non-circular shape of the guiding mandrel serves as anti-rotation constraint to ensure a specific shape or configuration of the collapsible device when it is being deployed. However, this is different from the above-mentioned technical effect - a specific rotational orientation of the collapsible device at the delivery site is not required in E2.

The Board does not accept the appellant's approach of defining two independent and unrelated partial problems to be solved by features f) and g), viz. impeding rotation of the collapsible device on the one hand and alignment with the anatomical structure on the other hand. Feature g) does not only require a fixed bend, but also that the single orientation of the alignment member and thus the collapsible member (defined in feature f)) is set relative thereto, which implies an interrelation between the two features.

Accordingly, the fact that E2 teaches that the delivery catheter (62) (which is different from the guiding mandrel corresponding to the claimed pusher catheter as explained above) may comprise a bend as shown in Figures 14A and 14B for facilitating the steering of the delivery system through the passageways (page 18, lines 31 to 33), does not lead to feature g), let alone to the combination of feature f) and g). It follows that the subject-matter of claim 1 is not obvious from E2 alone in view of the common technical knowledge.

Also in E1, the orientation of the (rotationally symmetric) collapsible device (50) at the delivery site is of no importance and not addressed anywhere. E1 also discloses a catheter sheath (105) comprising a curve for directing its distal end to the delivery site as described in paragraph [0040], but this sheath does not correspond to the claimed pusher catheter. The pushing of the collapsible device (50) is achieved by means of a guidewire (95 or 117) located within this sheath, as explained in paragraphs [0041] and [0048]. Similar to the mandrel (42) of E2, the guidewire is also bent under these circumstances, but it does not comprise a **fixed** bend as defined in feature g) (such a fixed bend in the guidewire of E1 would even impede the advancement of the guidewire within the sheath). Contrary to the appellant's view, the term "fixed" does constitute a limiting feature over the disclosure of E1. Furthermore, the Board does not share the appellant's opinion that it makes no difference whether it is the catheter sheath or the guidewire itself which is bent.

Moreover, E1 also fails to disclose feature f). The ball or pusher button (120) of the guidewire (117) to which the occlusive device (50) is attached as described in paragraphs [0042] and [0043] does not allow only one orientation thereof. The passage in paragraph [0049] cited by the appellant with respect to the threaded flange (70) of the occlusive device relates to its engagement with a removal device, and not with the guidewire which serves as a pusher device.

Accordingly, when starting from E2 and taking into account the teaching of E1, the subject-matter of claim 1 is not rendered obvious for the skilled person

since E1 does not address the above-mentioned problem and technical advantages and also fails to disclose the distinguishing features f) and g).

Under these circumstances, the appellant's obviousness objection with E1 selected as a starting point and combined with E2 cannot be successful either. Moreover, E1 is more remote than E2 since the guidewire (97 or 117) cannot be equated to a pusher **catheter** as defined in feature a) of claim 1. The disclosed catheter (105), on the other hand, fails to disclose features c) to e).

Accordingly, the subject-matter of claim 1 of the main request is inventive within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated